No. 3745 P. 1

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Regarding the follo	owing Application:		
Applicant(S):	STEINER, Mitchell S. et al.	Examiner:	FUBARA, BLESSING M
Serial No./ Patent No.:	10/747,685	Group Art Unit:	1618
Filed/Issued Date:	December 30, 2003	Attorney Docket No.:	P-2769-US10
Title:	A METHOD FOR CHEM	MOPREVENTION O	F PROSTATE CANCER
Transmittal Sheet of Containing: Pages of Sp Pages of Cl Page of Ab: Pages of F Pages of F Signed Declaration Request for Correct Recordation Cov Copy of Notice of	ication Transmittal iheet ect Under 35 USC 111(a) Application Under 35 USC 111(b for Entering National Phase secification laims stract formal Drawings A Power of Attorney tion of Recordation of Assign. and	10. Response to Not 11. Request for Cot 12. Information Dis Form PTO/SB 13. Preliminary An 14. Response to Off dated 15. Petition for a Ot 16. Notice of Appeal 17. Issue Fee Trans 18. Submission of F Submission of F Copy of Priority 20. Claim for Conv 12. Revocation and	ne Month(s) Extension of Time Month(s) Extension of Time Month(s) Extension of Time Publication Fee Month(s) Two sets of Intaining Figs.

AUG 0 8 2007

Attorney Docket No.: P-2769-US10

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):

STEINER, Mitchell S. et

Examiner:

FUBARA, BLESSING M

Serial No.:

10/747,685

Group Art Unit:

1618

Filed:

December 30, 2003

Title:

A METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER

Mail Stop Amendment Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO/SB/08:

- 1. A listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents and/or United States patent application publications are not included in this information disclosure statement; and/or
- 2. Itsting documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. 10/611.056, filed November 8, 2000, which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
- 3. Isting documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;
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STEINER, Mitchell S., et al

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Page 2

December 30, 2003

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

į	I)		Within three (3) months of filing the subject Application or entry of the subject
	App	lication i	nto the national stage or before mailing of the first Office Action on the merits of
	the	subject .	Application or a request for continued examination thereof, whichever event
:	occu	ırs last p	ursuant to of 37 C.F.R §1.97 (b); or
		57	and the second of the second o

- II) After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;
 - the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(o) more than three (3) months prior to the filing of this information disclosure statement; or

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SERIAL NO.:

STEINER, Mitchell S., et al

10/747,685

December 30, 2003

FILED: Page 3

	2.	the undersigned hereby authorizes the Patent Office to charge the fee in						
	the a	mount of \$180.00 under 37 C.F.R §1.17 (p) to Deposit Account 50-3355.						
ш)		After the period in (I) and (II) but before the payment of the issue fee and,						
	1.	The undersigned hereby states:						
		a)						
		cited in a communication from a foreign Patent Office in a counterpart						
	foreign application not more than three (3) months prior to the fil							
		Information Disclosure Statement; or						
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		application, and to the knowledge of the undersigned after making reasonable						
		inquiry, no item of information contained in this Information Disclosure						
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		than three months prior to the filing of this Information Disclosure Statement;						
		· and						
	2.	The undersigned hereby authorizes the Patent Office to charge the						
		ion fee in the Amount of \$180.00 under 37 C.F.R §1.17 (p) to Deposit Account						
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Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Adopunt No. 50-3355.

Respectfully submitted.

Mark S. Cohen

Attorney/Agent for Applicant(s)

Registration No. 42,425

Dated: August 7, 2007

Pearl Cohen Zedck Latzer, LLP 1500 Broadway, 12th Floor New York, New York 10036

Tel: (646) 878-0800 Fax: (646) 878-0801

PEARL COHEN ZEDEK LATZER

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	Substitute	for form	1449A/PTO	Com	Complete if Known		
				Application Number	10/747,686		
INFO	RMA	TION	DISCLOSURE	Filing Date	December 30, 2003		
STATEMENT BY APPLICANT (use as many sheets as necessary)				First Named Inventor	STEINER, Mitchell S.		
				Group Art Unit	1614		
				Examiner Name	Not yet known		
Sheet	1	of	10	Attorney Docket Number	P-2769-US10		

		U.	S. PATENT DOCUMENTS		
Examiner nitials*	Cite, No.	U.S. Patent Document Number Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	٨	4,990,538	Harris et al.	February 5, 91	
	В	5,788,964	Baral ct al.	August 4, 98	~
	C	5,650,425	Blegnon et al.	July 22, 97	
	D	4,696,949	Toivola et al.	Sept 29, 87	
	Ŀ	5,491,173	Toivola et al.	Feb. 13, 1996	
	F	5,571,534	Julonen et al.	Nov. 5, 1996	
	G	5,605,700	DeGregorio et al.	Fcb. 25, 1997	
	H	5,595,722	Grainger et al.	Jan. 21, 1997	
	1	5,599,844	Grainger et al.	Feb. 4, 1997	
	J	5,629,007	Audia et al.	May 13, 1997	
	K	5,635,197	Audia et al.	June 3, 1997	
	<u>l.</u> .	5,595,985	Labrie	Jan. 21, 1997	·
	М	5,441,986	Thompson, et al	August, 15, 1995	
	N	5, 859, 045	Treppendahi, et al	January 12, 1999	
	O 1	5, 935, 987	Treppendahl, et al	August 10, 1999	•
	Ë	6,899,888	Steiner, et al	05-2005	
	Ö	2006/0019989	Steiner, et al	01-2006	
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	Ü	2006/0270641	Steiner, et al	11-2006	
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	38	2004/0096510	Steiner, et al	05-2004	
	×	2003/0153625	Steiner, et al	08-2003	

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INFO	ORMAT	ION	DISCLOSURE	Filing Date	December 30, 2003	
STA	TEME	NT B	Y APPLICANT	First Named Inventor	STEINER, Mitchell S.	
i				Group Art Unit	1614	
(4	use as mai	ny shee	its as necessary)	Examiner Name	Not yet known	
Sheet	2	of	10	Attorney Docket Number	P-2769-US10	

			FORE	IGN PATENT DOCUME	ENTS		
Examiner Initials*	Cite, No.1		gnPatent Document Kind Code ⁵ Number (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T®
	Y	wo	98/58634	Degregorio, et al	December 30, 1998		
	7.	EP	415 623 A2	Harris et al	March 6, 1991		
	AA	EP	616 529 B1	Jalonen, et al	September 28,1994		
	AB	EPC	095875	Toivola, et al	Dec 7, 1995		
	ΛC	wo	95/26720	Bicgon et al	Oct 12, 1995		
	ΛD	wo	0008001	Huehner, et al	Feb 17, 2000		
	ΛĽ	wo	95/26720	Bicgon, et al	October 12, 1995	,	
	AF	wo	00/19998	KGK SYNERGIZE	April 13, 2000		
•	AG	wo	97/25038	NOVO NORDISK	July 17, 1997		
	ΛIJ	wo	99/08682	DUKE UNIVERSITY	February 25, 1999		$\perp \perp$
•	Λı	wo	97/25037	NOVO NORDISK	July 17, 1997	.]	

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Substitute for form 1449A/PTO				Complete if Known		
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INF	ORMA	TION	DISCLOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT				First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1614	
(use as many sheets as necessary)				Examiner Name	Not yet known	
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			U.	S. PATENT DOCUMENTS		
Examiner Initials*	Cite,	U.S. Patent Number	Document Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	. AJ	4,329,364		Neri et al.	May 11, 1982	
	AK	4,474,813		Neri et al.	Oct. 2, 1984	
	AL	6,080.877		Swindell et al	June, 2000	
	MA	6,265,448		Steiner et al	July 24, 2001	
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	AO	6,632,447	1	Steiner et al	Oct 14, 2003	
	Λl	6,413,533		Steiner et al	July 2, 2002	
	AQ	6,413,534		Steiner et al	July 2, 2002	
	AR	6,413,535		Steiner et al	July 2, 2002	,
··· .	AS	4,996,225		Toivola et al	Feb 26, 1991	
	ΛT	5,811,120		Gibson et al	Sept 22, 1998	
	λU	5,972,383		Gibson et al	Oct 26, 1999	
	ΛV	4.418.068		Jones	Nov 29, 1983	<u> </u>
	AW	5,852,059		Thompson, ct al	December 22, 1998	· · · · · · · · · · · · · · · · · · ·
	AX	5,827,892		Locser, ct al	October 27, 1998	
	AY	5,821,254		Span, et al	October 13, 1998	

Examiner Initials*		Forei	ignPatent Docum	nent	J	Date of Publication of		T
	Cite, No. 1	Office ³	Number (if kno	lode ⁵	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Pagea, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т
	AZ.	wo	94/12162		Warri et al	June 9, 1994		C
	BA	wo	99/56739		Steiner et al	November 11, 1999		C
	BB	wo	00/47214		Healey et al	August 17, 2000		
	BC	wo	96/09046		Audia et al	March 28, 1996		
	BD	EP .	0 670 162	1	Gibson et al	Sept 6, 1995		

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	Substitute	for form	1449A/PTO	Complete if Клоwп	
				Application Number	10/747,685
INF	ORMA	TION	DISCLOSURE	Filing Date	December 30, 2003
STATEMENT BY APPLICANT				First Named Inventor STEINER, Mitchell S	STEINER, Mitchell S.
		•		Group Art Unit	1614
(use 49 ms	ny she	ets as necessary)	Examiner Name	Not yet known
Sheet	4	of	10	Attorney Docket Number	P-2769-US10

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T°
	BE	Greenwald "Expanding Horizons in Breast and Prostate Cancer Prevention and Early Detection", in J. Cancer Falucation, 1993, Vol. 8, No. 2, pages 91-107.	
	BF	Brawley et al., "Chemoprevention of Prostate Cancer" in Urology, 1994, Vol. 43, No. 5.	
	BG	Kelloff et al., "Introductory Remarks; Development of Chemopreventive Agents for Prostate Cancer" in Journal of Cellular Biochemistry, 1992, Supplement 16H: 1-8.	
	ВН	Lucia et al., "Chemopreventive Activity of Tamoxifen, N-(4-Hydroxyphenyl)retinamide, and the Vitamin D Analogue Ro24-553 1 for Androgen-promoted Carcinomas of the Rat Seminal Vesicle and Prostate" in Cancer Research, 1995, vol. 55, pages 5621-5627.	
	BI	Potter et al., "A Mechanistic Hypothesis for DNA Adduct Formation By Tamoxifen Pollowing Hepatic Oxidative Metabolism" in Carcinogenesis, 1994, Vol. 15, No. 3, pages 439-442.	
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	вк	Martel Celine et al. "Binding Characteristics of Novel Nonsteroidal Antestrogens to the Rat Uterine Estrogen Receptors", Pergamon, J. Steroid Biochem. Molec. Bio. Vol 64, No. 3-4, pp. 199-205, 1998.	
	BL	Valavaara Ritva, MD, PhD "Reliability of Estrogen Receptors in Predicting Response To Antiestrogens", Oncology, Volume 11 Number 5 Supplement No. 4 p. 14-18.	
	ВМ	Richard Gams, MD "Phase III Trials of Toremifene vs Tamoxifen" Oncology Volume 11, Number 5, Supplement 4, May 1997	
		Christian Rohlff et al. "Prostate Cancer Cell Growth Inhibition by Tumoxifen Is Associated With Inhibition of Protein Linase C and Induction of p21" The Prostate 37:51-59 (1998) ©1998 Wiley-Liss, Inc	
	во	Nevalanine et al. "Hormone Regulation of Human Prostate in Organ Culture" Cancer Ress, vol. 53, no. 21, 1993, pages 5199-5207, XO002117653.	
	BP	Gingrich et al., "Andrugen-independent Prostate Cancer Progression in the TRAMP Model", in Cancer Research 57, November 1, 1997, pages 4687-4691.	
	BQ	Gingrich et al., "Pathalogic Progression of Autochthonous Prostate Cancer in the TRAMP Model", Prostate Cancer and Prostatic Diseases, 1999, 2, Pages 70-75.	
	BR	Gingrich et al., "Metastatic Prostrate Cancer in a Transgenic Mouse", in Cancer Research 56, September 15, 1996, pages 4096-4102.	
	AS	Gershamovich et al., "A Phase III Comparison of Two Toremifene Doses to Tamoxifen in Postmenopausal Women with Advanced Breast Cancer", Breast Cancer Research and Treatment 45, 1997, Pages 251-262.	

Examiner	•	Date	
Signature		Considered	

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant.

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INFORMATION DISCLOSE	RE Filing Date	December 30, 2003	
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(use as many sheets as necessary	Examiner Name	Not yet known	
Sheet 5 of 10	Attorney Docket Number	P-2769-US10	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	τ2
,	BT	Hayes et al. "Randomized Comparison of Tamoxifen and Two Separate Doses of Toremifenein Postmenopausal Patients with Metastatic Breast Cancer", Journal of Clinical Oncology, Vol. 13, No. 10, 1995, pages 2556-2566.	
	BU	Pyrhönen et al., "Comparison of Toremifene and Tamoxifen in Postmenopausal Patients with Advanced Breast Cancer: a Randomized Double-blind, the 'Nordie' Phase III Study". British Journal of Cancer, 1997, 76(2), pages 270-277.	
	BV	Neubaner et al., "Endocrine and Antiprostatic Effects of Raloxilene (LY156758) in the Male Rat", The Prostate 23, 1993, pages 245-262.	
	вw	Pollard, "Prevention of Prostate-Related Cancers in Lobund-Wistar Rats", The Prostate 39, 1999, pages 305-309.	
	BX	Simard et al., "Keoxifene Shows Pure Antiestrogenic Activity in Pituitary Gonadotrophs", Molecular and Cellular Endocrinology 39, 1985, pages 141-144.	- ·
	BY	Perry "High Dose Toremifene for Estrogen and Progesterone Receptor Negative Metastatic Breast Cancer: a Phase II Trial of the Cancer and Leukemia Group B (CALGB)", in Breast Cancer Res Treat - 1995; 26(1): 25-40	
	BZ	Hietamen T "Open Phase II Study of High-Duse Toremifene as First-Line Therapy for Advanced Breast Cancer" in Oncology - May 1997; 11(5 Suppl 4); 37-40.	
,	CA	Black et al. "Uterine Bloassay of Tamoxifen, Trioxifene and a New Estrogen Antogonist (LY117018) in Rats and Mice" in Life Sciences, 1980, Vol. 26, pp. 1453-1458	
	СВ	Moore et al. "Regulation of Cytoplasmic Dihydrotestosterone Binding in Dog Prostate by 17?- Estadiol", in J. Clin. Invest, © The American Society for Clinical Investigation, Inc., Vol. 63 March 1979, pages 351-357.	
	CC	Shirai et al. "Effects of Testosterone, Dihydrotestosterone and Estrogen on 3,2'-Dimethyl-4- Aminobiphenyl-Induced Rat Prostate Carcinogenesis" in Int. J Cancer: 57, 224-228 (1994)	
	CD	Greenwald et al. "Breast Cancer Prevention and Early Detection", pages 93-106.	
	CE	Shenfeld et al. "Androgen Deprivation Therapy", Chapter 37, Section III/Prostate Cancer, pages 467-477	
	CF	Jordan VC "Toremifene As An Anticancer Agent", Cancer Invest 1990; 8(2) 271	Τ'''
	CG	Karlsson S. et al. "A Two-Year Dietary Carcinogenicity Study Of The Antiestrogen Toromifene In Sprague-Dawley Rats" Drug Chem Toxicol 1996 Nov; 19(4): 245-66.	\top
	СН	Powles TJ "Status Of Antiestrogen Breast Cancer Prevention Trials" Oncology (Huntingt) 1998 Mar; 12(3 Suppl 5): 28-31.	
	CI	Moon RC et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Torumifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Res 1994 May-June; 14(3A): 889-93.	

Examiner	Date
Signature	Considered

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	Group Art Unit	1614		
(use as many sheets as necessary)	Examiner Name	Not yet known		
Sheet 6 of 10	Attorney Docket Number	P-2769-US10		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	₹2
	C1	Nevalainen MT et al. "Expression and Hormone Regulation Of Prolactin Receptors in Rat Dorsal and Lateral Prostate", Endocrinology 1996 Jul; 137(7): 3078-88.	
	СК	Foekens JA et al. "Expression Of Prostate-Specific Antigen (PSA) Correlates With Poor Response To Tamoxifen Therapy In Recurrent Breast Cancer", Br J Cancer 1999 Feb; 79(5-6): 888-94.	
•	ĺ	Brandes LJ et al. "Salutary Clinical Response Of Prostate Cancer To Antiandrugen Withdrawal; Assessment Of Flutamide In An In Vitro Paragdigm Predictive Of Tumor Growth Enhancement", Clin Cancer Res 1997 Aug; 3(8): 1357-61.	-
•		Miyata E et al. "Effects Of Tamoxifen, An Antiestrogen, On Rat Prostate Carcinogenesis by 3,2'- Dimethyl-4-Aminobiphenyl And Testerone Do Not Support An Estrogen Role in Testerone Promotion", Prostate 1997 Apr 1;31(1)9-13.	
_	CN	Pienta KJ et al. "A Phase II Evaluation Of Oral Tamoxifen And Intermittent Intravenous Vinblastine In Hormone-Refractory Adenocarcinoma Of The Prostate"., Am I Clin Oncol 1996 Oct; 19(5):500-3.	
	CO.	Picnta KJ et al. "Inhibition Of Prostate Cancer Growth By Vinblastine And Tamoxifen", Prostate 1995 May; 26(5): 270-4.	
	CP	Lippman SM et al. "Cancer Chemoprevention", J Clin Oncol 1994 Apr; 12(4):851-73.	\top
*		Szarku CE et al. "Chemoprevention Of Cancer", Curr Probl Cancer 1994 Jan-Feb; 18(1):6-79.	
	CR	Bergan RC et al. "A Phase II Study Of High-Dose Tamoxifen in Patients With Hormone-Refractory Prostate Cancer." Clin Cancer Res 1999 Sep; 5(9): 2366-73.	
	CS	Chang William V et al. "Estrogen Receptor-7: Implications For The Prostate Gland" The Prostate 40:115-124 (1999)	
.•		Shughruz Paul I. et al. "Comparative Distribution Of Estrogen Receptor-? (Er-?) And ? (Er-?) mRNA In The Rat Pituitary, Gonad, And Reproductive Tract" Steroids 63: 498-504, 1998, Elsevier Science Inc.	
•	L	Prins Gail S. et al, "Neonatal Estrogen Exposure Up-Regulates Estrogen Receptor Expression In The Developing And Adult Rat Prostate Lobes*", Endocrinology 138: 1801-1809, 1997)	
	CV	Hempstock J. et al. "Growth Inhibition Of Prostate Cell Lines In Vitro By Phyto-Oestrogens", British Journal Of Urology (1998), 82, 560-563.	1
		Awoniyi Caleb A. et al. "Neonatal Exposure To Coumestrol, A Phystocstrogen, Does Not Alter Spermatogenic Potential In Rats", Endocrine, vol. 7, no. 3, 337-341, December 1997.	-
·	CX	"Chemoprevention Of Prostate Cancer: Guidelines For Possible Intervention Strategies", Journal of Cellular Biochemistry, Supplement 16H:140-145 (1992).	†

Examiner	Date	
Signature	Considered	
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^{*} EXAMENER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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,	Substitute	for form	1449A/PTO	Complete if Known	
				Application Number	10/747,685
INF	ORMA	TION	DISCLOSURE	Filing Date	December 30, 2003
STATEMENT BY APPLICANT			Y APPLICANT	First Named Inventor	STEINER, Mitchell S.
				Group Art Unit	1614
(use as many sheets as necessary)			ets es necessary)	Examiner Name	Not yet known
Sheet	7	of	10	Attorney Docket Number	P-2769-US10

		NON PATENT LITERATURE DOCUMENTS	
Examiner nitials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	CY	"When Is Intervention Warranted?", Journal Of Cellular Biochemistry, Supplement 1611:138-139 (1992).	
	CZ.	"Editorial: A New Actor In The Estrogen Receptor Drama-Entre ER-?", Endocrinology Vol. 138, No. 3, (1997).	
	DA	Kuiper George G. J. M. et al. "Comparison Of The Ligand Binding Specificity And Transcript Tissue Distribution Of Estrogen Receptors 7 and 7", Endocrinology Vol. 138, No. 3, 863-870 (1997).	
•	DB	Colletta Anthony A. et al. "Alternative Mechanisms Of Action Of Anti-Oestrogens" Breast Cancer Research and Treatment 31: 5-9, 1994.	
	DC	Grilliths K. et al. "Further Insights Into Endocrine Disease - Diet and Prostate Disease" An IPHC Teaching Programme.	-
	DD	Yu H et al. "Induction Of Prostate Specific Antigen Production By Steroids And Taxoxifen In Breast Cancer Cell Lines", Breast Cancer Res Treat 1994; 32(3)291-300.	
	DE	Horton J et al. "Tamoxifen in Advanced Prostate Cancer: An ECOG Pilot Study", Prostate 1988; 12(2):173-7.	
	DF	Kangas I. "Development And Biochemical Pharmacology Of Toremifene, An Antiestrogenic Antitumor Drug", Acta Obstet Gynecol Scand 1991; 70(4-5): 399.	
	DG	Anttila M et al. "Pharmacokinetics Of The Novel Antiestrogenic Agent Totemifene in Subjects With Altered Liver And Kidney Function" Clin Pharmacol Ther 1995 Jun; 37(6):628-35.	
•	DH	Kamut AM et al. "Chemoprevention Of Urological Cancer", The Journal Of Urology, Vol. 161, 1748-1760. June 1999, p. 1748-1760.	
	וֹמ	Fleton SA "Potential New Anticstrogens For The Treatment Of Breast Cancer", Highlights in Oncology Practice Vol. 15, No. 2, 1997 p. 47-52	
	ומ	Nevalainen M.T. et al. "Estrugen and Prolactin Regulation of Rat Dorsal and Lateral Prostate in Organ Culture", Endocrinology, Vol. 129, No. 2 pages 612-618	
	DK	Moon R.C. et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tumoxifen, Aminoglutethlinide and Progesterone", Anticancer Research 14: 889-894 (1994)	
	DΙ.	Price K. R. et al. "Naturally Occurring Oestrogens in Food - A review", Food Additives and Contaminants, 1985, Vol. 2, No. 2, 73-106.	

Date
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¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449	VPTO	Complete if Known		
		Application Number	10/747,685	
INFORMATION DIS		Filing Date	December 30, 2003	
STATEMENT BY A	PPLICANT	First Named Inventor	STEINER, Mitchell S.	
		Group Art Unit	1614	
(use as many sheets as	necessery)	Examiner Name	Not yet known	
Sheet 8 of 10		Attorney Docket Number	P-2769-US10	

	_	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	tnclude name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, calatog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	DM	Cheng E et al. "Endocrinology Of The Prostate", Presente Diseases, chapter 5- p. 57-71.	
*	DN	Bonkhoff H et al. "Estrogen Receptor Expression in Prostate Cancer and Premalignant Prosatic Lesions", American Journal of Pathology, Vol. 155, No. 2 August 1999.	
•	DO	"New Research Approaches In The Prevention And Cure Of Prostate Cancer", American Association For Cancer Research, December 1998	
	DP	Xiaolin Zi et al. "Silibinin Decreases Prostate-Specific Antigen With Cell Growth Inhibition Vla G1 Arrest, Leading To Differentiation Of Prostate Carcinoma Cells: Implications For Prostate Cancer Intervention; Proc. Nsil. Acad. Sci, USA Vol. 96, pp. 7490-7495, June 1999. Medical Sciences.	-
•	DQ	Landstrom M, et al. "Inhibitory Effects Of Soy and Rye Dicts On The Development Of Dunning R3327 Prostate Adenocarcinoma in Rats, The Prostate 36: 151-161 (1998).	
:	DR.		
•	DS	Treinen KΛ et al. "An Evaluation Of The Novel Selective Estrogen Receptor Modulator, Idoxifene, For Effects On Reproduction in Rats And Rabbits:, Toxicol Sci 1998 Feb; 41(2):199-207.	-
	TO	Boehm S et al. "Extrogen Suppression As A Pharmacotherapeutic Strategy In The Medical Treatment Of Benign Proximite Hyperplasia: Evidence For its Efficacy From Studies With Mepartricin" Wien Klin Wochenschr 1998 Dec 11; 110(23):817-23.	
-	ווט	Dhar JD et al. "Estrogen, Androgen and Antiestrogen Responses in The Accessory Organs Of Male Rats During Different Phases Of Life", Endocr Res 1998 May; 24(2): 159-69.	
	DV	West Neal B et al. "Estrogen and Progestin Receptors And Aromatase Activity In Rhesus Monkey Prostate" Endocrinology, Vol. L. 123, (1998)	
	DW	Strauss L "Genistein Exerts Estrogen-Like Effects In Male Mouse Reproductive Tract", Molecular and Cellular Endocrinology 144 (1998) 83-93, Elsevier Science Ireland Ltd.	

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Examiner	• •	Date	
Signature			
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Substitute for form 1449A/PTO			1449A/PTO	Complete If Known		
				Application Number	10/747,585	
INF	DRMAT	ΓΙΟΝ	DISCLOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT				First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1614	
(use as many sheets as necessary)			its as necessary)	Examiner Name	Not yet known	
Sheet	9	of	10	Attorney Docket Number	P-2769-U\$10	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(a), publisher, city and/or country where published.	Τ [‡]
	DX	Hobisch Alfred "Metastatic Lesions From Prostate Cancer Do Not Express Oestrogen And Progesterone Receptors" J. Pathol. 182: 356-361, 1997.	
	DZ	Albert David S. et al. "An Overview Of Clinical Cancer Chemoprevention Studies With Emphasis On Positive Phase III Studies" Overview of Diet Cancer 6928-6975 (1995)	
	EA	Strom Sara S. et al. "Phytoestrogen Intake and Prostate Cancer: A Case-Control Study Using A New Database", Nutrition and Cancer, 33(1), 20-25. (1999).	
	ЕB	Kellof GJ et al "Strategies For Chemoprevention Of Prostate Cancer", Prostate Cancer and Prostate Disease (1988) 5, 107.	
	EC	Buelke-Sam Judy et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology and Reproductive Development Testing", Reproductive Toxicology Vol. 12, No. 3 pp. 217-221, 1998.	
	ED	Prins Gail S. "Developmental Estrogenization Of The Prostate Gland", Prostate:Basic and Clinical Aspects p. 245-263 (1997).	
	EF	Kuiper George G. J. M. "Cloning Of A Novel Estrogen Receptor Expressed In Rat Prostate And Ovary", Proc. Natl. Acad. Sci USA Vol. 93, pp. 5925-5930, June 1996 Biochemistry.	
	EG	Kuiper George G. J. M. "Interaction Of Estrogenic Chemicals and Phytoestrogens With Estrogen Receptor?", Endocrinology Vol. 139, No. 10 (1998).	
-	ЕН	Horton John et al. "Tamoxifen In Advanced Prostate Cancer" An ECOG Pilot Study", The Prostate 12: 173-177 (1988).	
	हा	Hayes "A Randomized Comparison Of Tamoxifen, Trioxifene And A New Estrogen Antogonist (LY117018) In Rats And Mice" In Life Sciences, 1980, vol. 26, pp. 1453-1458.	•
	ĒJ ¯	Jordan Craig V. "Antiestrogenic Action of Reloxifene and Tamoxifen: Today and Tomorrow" Journal of National Cancer Institute, Vol. 90, No. 13, July 1, 1998	•
•	EK	Warri Anni. M. et al "Apoptosis in Toremifene Induced Growth Inhibition of Human Breast Cancer Cells in Vivo and In Vitro" Journal of National Cancer Institute, Vol. 85, No. 17, September 1, 1993	
	1 1	Mobbs, B.G. et al "Concentration and Cellular Distribution of Androgen Receptor in Human Prostatic Neoplasia: Can Estrogen Treatment Increase Androgen Receptor Content?" J. Steroid Blochem. Vol. 19, No. 3 pp. 1279-1290, 1983.	

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Signature		Considered	1

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Substitute for form 1449A/PTO				Complete If Known		
			•	Application Number	10/747,685	
INF	ORMAT	TION	DISCLOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT				First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1614	
(use as many sheets as necessary)			His as necessary)	Examiner Name	Not yet known	
Sheet	10	of	10	Attorney Docket Number	P-2769-U810	

		NON PATENT LITERATURE DOCUMENTS	_
Examiner nitials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	7
	ЕМ	Krieg, Michael et al "Androgens and Estrogens: Their Interaction with Stroma and Epithelium of Human Benign Prostatic Hyperplasia and Normal Prostate" J. Steroid Biochem. Vol. 19, No. 1 pp. 155-161, 1983	
	EN	Hard, Gordon C, et al. "Major Difference in the Hepatocarcinogenicity and DNA Adduct Forming Ability between Toremifene and Tamoxifen in Female Crl: CD(BR) Ruts" Cancer Research 53, 4534-4541, October 1, 1993	
	EO	Royle Peter et al "Epidemiology of Prostate Cancer Chemoprevention" Eur Urol 1999: 35:370-376	
	EP	Bostwick, David G. et al "Reversibility of Prostatic Intraepithelial Neoplasia; Implications for Chemoprevention" Eur. Urol 1999: 35:492-495	
	EQ	Bostwick David "Prospective Origins of Prostate Carcinoma" American Cancer Society 1996	
	ER	The Lancet "The Challenge of Breast Cancer" Vol. 342, September 18, 1993	_
	ES	Zaridze, David G. et al "International Trends in Prostatic Cancer" Int. J. Cancer: 33, 223-230 (1984)	
•	हा	Nevalsinen MT et al "Hormone regulation of human prostate in ดายูลก culture" Cancer Res. 1993 Nov. 1:53 (21):5199-207	
•	ΕU	Steiner, et al "Selective Estrogen Receptor Modulators for the Chemoprevention of Prostate Cancer." Urology 2001 57 (4 Suppl. 1) 68-72	
	EV	Raghow, et al "l'oremifene prevents prostate cancer in the transgenice adenocareinoma of mouse prostate model." Cancer Res. 2002 1;62(5): 1370-1376	
	EW	Steiner, et al "Anticstrogens and selective estrogen receptor modulators reduce prostate cancer risk" World J. Urol. 2003 21 (1):31-6	
	EX	Neubauer, et al "Raloxifene (LY156758) produces antimetastatic responses and extends survival in the PAIII rat prostatic adenearcinoma model." Prostate 1995 27(4)220-9.	_
	EY	Pylkkanen, et al "Animal models for the prencoplastic lesions of the prostate." Eur Urology 1996;30(2)243-8	
	EZ	Schneider, et al "Nonsteroidal antiestrogens and partial estrogens with prostatic tumor inhibiting activity." J. Cancer Res. Clin. Oncol. 1986; 112(3)258-65.	
	FA	Schneider, et al "Effect of zindoxifene on experimental prostatic turnours of the rat. J Cancer Res. CLin. Oncol. 1991;117(1) 33-6	
	FB	lp, et al "Funtionality of estrogen receptor and tamoxifen treatment of R3327 Dunning rat prostate adenocarcinoma." Cancer Res 1980 40(7) 2188-93	

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